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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/509,910 | 04/03/2000 | WALTER SEBALD | LEA32545 | 6688 |

7590 05/21/2002

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/21/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/509,910 | SEBALD, WALTER | |
| | Examiner | Art Unit | |
| | Jegatheesan Seharaseyton | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 March 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 5-9 is/are pending in the application.

4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 3/05/02 in Paper No. 12. Previously pending claims 1-4 claims have cancelled. Newly added claim 9 is pending.
2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed is required.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
4. All 35 USC § 112 rejections from Paper No. 11 have been withdrawn due to Applicant's remarks. 35 USC § 102 rejections have been withdrawn because Applicant has elected to cancel the previously pending claims.
5. The following are new grounds of rejection necessitated by applicant's amendment.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6a. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. (1993) in view of Duschl (1995).

The instant invention is directed to hIL-4 mutein proteins that have reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor and/or HIL-13R α subunit of the hIL-4 receptor.

Kruse et al. teaches production of the muteins of IL-4 R121D, K123D, Y124D, S125D in *E.coli*. They measured receptor affinities of the variants are during competitive radioligand binding to Raji cells (Table 1). However, Kruse et al. does not discuss the altered specificity of the muteins/variants.

Duschl discloses the mutations in the IL-4 signaling site prevent association of γ c, but not binding to IL-4R α using conventional binding studies. This demonstrates that intact signaling site of IL-4 is required to recruit γ c into the receptor complex (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to analyze the muteins of the instant inventions as disclosed in Kruse et al. and Duschl et al. to study the change in affinity and specificity to the various subunits, because Kruse et al. teaches that identifying the affinity and specificity will allow for the rational design of high affinity IL-4 antagonist. Therefore, the instant invention is obvious over Kruse et al. (1993) in view of Duschl (1995).

7. No claims are allowed.

8. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

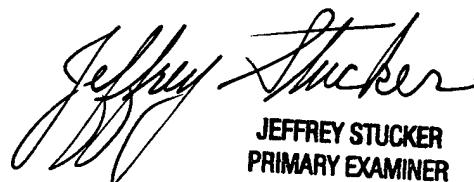
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
May 17, 2002



JEFFREY STUCKER
PRIMARY EXAMINER